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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,567	02/19/2004	Mostafa Fatemi	630666.90822	5652

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EXAMINER	
MARMOR II, CHARLES ALAN	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,567	FATEMI, MOSTAFA	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) 9-12 is/are allowed.

6)☒ Claim(s) 1-8 and 13-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 2/19/04 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "64" included in Fig. 4; "79" included in Fig. 5; and "83" included in Fig. 6. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities:

a. In paragraph [0001], lines 2-3, the current status of the parent application should be provided.

b. In paragraph [0005], line 4, "can produce, and" apparently should be deleted.

c. In paragraph [0006], line 4, "a modulation" apparently should read --an audio--.

Appropriate correction is required.

Claim Objections

3. Claim 2 is objected to because of the following informalities: in line 8, "modulating" apparently should read --modulation--. Appropriate correction is required.

4. Claim 3 is objected to because of the following informalities: in line 5, --generator-- apparently should be inserted following "RF". Appropriate correction is required.

5. Claim 7 is objected to because of the following informalities: in lines 6 and 10, "being" apparently should read --adapted to be--. Appropriate correction is required.

6. Claim 8 is objected to because of the following informalities:

a. In line 1, "tracker" apparently should read --tracking device--.

b. In line 4, --ultrasound-- apparently should be inserted before "signal".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3 and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 3, the limitation "the ultrasound signal generator" recited in line 1 renders the claim indefinite. It is unclear whether inconsistent terminology has been used in an attempt to further limit "the ultrasound signal generation circuit" of claim 1 or if this is a separate and distinct element of the apparatus that lacks antecedent basis in the claims.

Claim 13 recites the limitations "the first ultrasound signal" in lines 7-8; "the second ultrasound signal" in lines 9-10; and "the first and second RF signals" in line 12. There is insufficient antecedent basis for these limitations in the claim. There is no first ultrasound signal, second ultrasound signal, first RF signal, or second RF signal recited in the claim prior to these recitations.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-8 and 15-16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 recites that an ultrasound transducer circuit is "acoustically coupled to the abdomen of a pregnant woman". This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively

recited. Therefore, applicant should amend the claim to recite that the ultrasound transducer circuit is --adapted to be acoustically coupled to the abdomen of a pregnant woman--.

Claim 5 recites that a fetal monitor probe is "acoustically coupled to the abdomen of the pregnant woman". This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, applicant should amend the claim to recite that the fetal monitor probe is --adapted to be acoustically coupled to the abdomen of a pregnant woman--.

Claim 8 recites that a receiving transducer is "acoustically coupled to the abdomen of the pregnant woman". This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, applicant should amend the claim to recite that the receiving transducer is --adapted to be acoustically coupled to the abdomen of a pregnant woman--.

Claim 15 recites that a fetal monitor probe is "acoustically coupled to the fetus". This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, applicant should amend the claim to recite that the fetal monitor probe is --adapted to be acoustically coupled to the fetus--.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claim 1, 3 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Fatemi-Booshehri et al. ('239). Fatemi-Booshehri et al. teach an acoustic force generator a first RF generator generating an ultrasound signal at a first frequency; a second RF generator generating an ultrasound signal at a second frequency; a first ultrasound transducer electrically coupled to receive the ultrasound signal the first generator; and a second ultrasound transducer electrically coupled to receive the ultrasound signal from the second generator. The difference between the first frequency and the second frequency may be within an audio frequency range. Each of the first and second ultrasound transducers are operable to convert one of the first and second ultrasound signals to a focused beam, respectively and are positioned to direct the first and second focused beams to intersect at a selected position. The acoustic force generator of Fatemi-Booshehri et al. meets all of the structural limitations of the claims and is capable of performing the intended use of the claim 13 of the present application by stimulating a fetus in utero should an operator of the device elect to position the intersection of the beams on a maternal abdomen.

13. Claim 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Prichep ('861). Prichep teaches an apparatus for producing a focused audio stimulation in a

maternal abdomen. The apparatus includes an ultrasound signal generation circuit (13) that produces at least one ultrasound signal to stimulate a fetus and an ultrasound transducer circuit (10). The ultrasound transducer circuit is electrically coupled to the ultrasound signal generation circuit and acoustically coupled to the abdomen of a pregnant woman. The transducer circuit receives the at least one ultrasound signal from the signal generation circuit and directs at least one focused ultrasound signal at a fetus to provide focused stimulation of the fetus. The apparatus also includes an event tracking device (15,20) for detecting a movement of the fetus. The movement of the fetus as determined by the event tracking device is capable of being correlated with the transmission of the ultrasound signal to verify the health of the fetus.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prichep ('861) in view of Durley, III ('629). Prichep, as discussed hereinabove, teach all of the limitations of the claims except that the event tracking device includes a fetal monitor probe and a Doppler fetal monitor. Durley, III teaches a portable ultrasonic Doppler system including a fetal monitor probe adapted to be acoustically coupled to the abdomen of the pregnant woman and a Doppler fetal monitor electrically coupled to the probe to monitor motion of the fetus. It would have been obvious to one having ordinary skill in

the art at the time Applicant's invention was made to use a Doppler fetal monitor similar to that of Durley, III with a focused audio stimulator similar to that of Prichep in order to monitor the reaction movements of the fetus in response to the audio stimulus.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1, 2 and 4-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6-8 and 10 of U.S. Patent No. 6,709,407. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the claims of the present application claim apparatus for providing focused stimulation to a fetus in a maternal abdomen, merely using different terminology to define essentially the same structural elements. Claims 1 and 2 of the present invention claim a substantially equivalent apparatus as recited in claim 1 of the patent. Claims 4 and 5 of the present invention claim a substantially equivalent apparatus as recited in claim 8 of the patent. Claims 6 and 7 of the present invention claim a substantially equivalent apparatus as

recited in claims 6 and 7 of the patent. Claims 6 and 8 of the present invention claim a substantially equivalent apparatus as recited in claim 10 of the patent. Since claims 1, 6-8 and 10 of the patent can be said to "anticipate" claims 1, 2 and 4-8 of the present invention, the aforementioned claims are not patentably distinct.

Allowable Subject Matter

18. Claims 9-12 are allowed over the prior art of record.

19. Claims 14-16 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, 2nd paragraph, and 35 U.S.C. 101 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

20. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 9-12, no prior art of record teach or fairly suggest a method for producing a localized sound in a maternal abdomen by placing first and second ultrasound stimulation transducers on a maternal abdomen and directing each of first and second focused beams at the head of a fetus in utero in order to form a stimulation signal at the intersection of the focal points, where a resultant force at an intersection of the focal points of the first and second focused beams vibrates the middle ear of the fetus in the audio range.

Regarding claims 14-16, no prior art of record teach or fairly suggest a stimulation device for stimulating hearing in a fetus in utero, where the stimulation

device includes a pair of RF generators; a pair of ultrasonic transducers arranged such that first and second focused beams respectively generated therefrom intersect at a position selected to stimulate a fetus; and at least one of a strip chart in combination with a strip chart marker and a fetal monitor probe in combination with a Doppler fetal monitor.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Francais ('834) teaches a system for imparting sensory effects across a mother's abdomen to a fetus and monitoring the effects on the fetus. Johnson ('814) and Alleyne ('044) teach fetal communication devices.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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November 17, 2004